In the Specification

Please amend pages 1; 3; 4; 10 to 13; and 19 to read as follows:

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TITLE OF THE INVENTION

Medical Gas Recirculation System

CROSS-REFERENCE TO RELATED APPLICATIONS

Not Applicable

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.

Not Applicable

THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.

Not Applicable

INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.

Not Applicable

BACKGROUND OF THE INVENTION.

Field of the Invention.

The present invention relates to an apparatus and method for recirculating at least a binary gas mixture to a medical device such as a cardiac pulmonary bypass oxygenator or an artificial ventilator.

More particularly the invention relates to an apparatus and method for controlling the composition, pressure and flow rate of a recirculating gaseous composition to a medical device, particularly to a cardiopulmonary bypass oxygenator, and recycling the gaseous composition.

Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98

Medical devices such as cardiopulmonary bypass oxygenators and artificial ventilators or respirators require a reliable and constant source of gas for safe and reliable operation for use during the relevant medical procedures.

Usually, the gaseous compositions used for procedures with such devices are various air/oxygen or nitrogen/oxygen mixtures, although in some situations, these devices may be used for administering other active agents to a patient.

For example, it is common to use a respirator for administering an anaesthetic agent to anaesthetise a patient prior to undergoing certain surgical procedures. Xenon is known for use as an anaesthetic agent.

US-6,131,571 (Lampotang et al) discloses a ventilation and/or anaesthesia delivery system having a recirculation circuit through which gas is circulated by a pump. Optionally, means are provided to introduce a liquid anaesthetic for vaporisation immediately downstream of the pump. After passage through a CO_2 absorber, bacterial filters, an optional heater or cooler and an optional manual breathing bag, the gas is delivered at a Y-piece connected to an endotracheal tube. The gas pressure at the Y-piece is controlled by a proportional flow control valve downstream of the Y-piece and operated in response to *inter alia* the gas composition at the distal end of the endotracheal tube. The size of an orifice in this valve is varied to alternately create (i) a pressure at the Y-piece that permits flow into the endotracheal tube and (ii) a pressure that permits gas flow from the tube into the circulation loop. In order to compensate for variations in gas flow between inhalation and exhalation, a volume reservoir is provided between the proportional control valve and the pump. Make-up gas is supplied via a pair of feed inlet valves in response to *inter alia* changes in the volume of recirculating gas in the reservoir. In order to provide for inhalation as well as exhalation, the gas feed to the pump is at subatmospheric pressure.

EP-A-0745405 (Siemens) discloses an anaesthetic system in which a breathing circuit can be switched between an open system and a rebreathing system. In the rebreathing system, a pressure-transfer unit applies rhythmic pressure changes to control the breathing of the patient. In the exemplified embodiment, the pressure-transfer unit is a bag and bottle as conventionally used in

the anaesthetic art.

EP-A-0861672 (Vladimirovna) discloses an inhalation apparatus having a recirculation circuit comprising a breathing bag, gas flow inducer; oxygen gas analyser; carbon dioxide gas analyser; temperature controller; gas flow switch; and absorbent filters. The gas flow switch provides for open cycle operation. Gas is supplied to a face mask by a gas inlet conduit controlled by an inhalation valve. Exhaled gas is returned to the recirculation circuit downstream of the inlet conduit via a microflora-removing device and an exhalation valve. A non-return valve is provided in the recirculation circuit between the inlet and outlet to the mask to prevent reversible of gas flow. Make-up gas is supplied by an inlet conduit upstream of the breathing bag. Oxygen is added via a valve responsive to signals from the oxygen and carbon dioxide gas analysers. Additional components are introduced into the feed conduit via respective valves but no detail of operation of these valves is provided. The gas flow inducer is stated to *reduce gasodynamic inhalation resistance by increasing the gas pressure* but no other details of its operation or construction are provided.

SU-A-1188638 (Dyachenko) discloses the use of ultrasonics to detect changes in gas composition.

US-A-4989597 (Werner) discloses an apparatus for administration of at least two gases, particularly oxygen and xenon, to a patient via a respiration apparatus comprising a patient circuit and a drive circuit. The patient circuit, which enables rebreathing of the gas to make maximal use of valuable gases, is provided with fresh gas input to replace exhaled carbon dioxide with oxygen and to supplement the xenon concentration. The drive circuit and the patient circuit are in open communication and the concentration of each of the components in the patient circuit is independently monitored and controlled by addition of small quantities of one or other of the gases. The open communication between the

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BRIEF SUMMARY OF THE INVENTION.

Accordingly, in a first aspect of the invention there is provided an apparatus providing and circulating to a medical device a medical gas mixture comprising at least two components, said

apparatus comprising:-

a main gas circuit for recirculating the medical gas and comprising:-

a constant speed circulation pump for pumping gas through the main circuit and increasing the gas pressure from a lower pressure to a higher pressure,

a pressure maintaining valve downstream of the pump and dividing the main circuit into a higher pressure section and a lower pressure section in order to maintain a constant pressure in the higher pressure section,

a medical gas outlet in the higher pressure section,

a spent gas inlet in the lower pressure section,

a first feed gas supply inlet, preferably located in the higher pressure section,

a second feed gas supply inlet, preferably located in the higher pressure section,

a concentration determining means for measuring the concentration of at least one component of the recirculating medical gas mixture and generating a signal indicative of said concentration,

circuit volume regulating means for varying the volume of the main circuit at a location in the lower pressure section for maintaining a predetermined gas flow to the pump and generating a signal indicative of said volume, and

means for venting gas from the main circuit;

a first feed gas supply conduit for supply to the first feed gas inlet of a first feed gas of predetermined composition;

first feed gas supply flow control means for controlling the flow of first feed gas through the first gas supply conduit in response to the signal from the

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concentration determining means to maintain constant the medical gas composition at the pump inlet;

a second feed gas supply conduit for supply to the second feed gas inlet of a second feed gas of predetermined composition different from the first feed gas;

second feed gas supply flow control means for controlling the flow of second feed gas through the second gas supply conduit in response to the signal from the circuit volume regulating means to maintain constant the recirculating medical gas composition; and

a medical device supply circuit for connecting the medical device to the main circuit to

receive a portion of the medical gas from the medical gas outlet thereof and to return spent gas to the spent gas inlet thereof and comprising:

flow control means for controlling flow of the medical gas to the medical device and

purification means for removing contaminant(s) from the spent gas.

In another aspect, the invention provides a medical device system comprising a medical device connected to the medical device supply circuit of an apparatus of the first aspect *supra*.

In a third aspect, the present invention provides a method of providing a medical device with a medical gas mixture comprising at least two components, said method comprising:-

recirculating the medical gas mixture in a main circuit having a higher pressure section maintained at constant pressure in series with a lower pressure section;

withdrawing a portion of the medical gas mixture from the higher pressure section and feeding said portion to the medical device;

removing contaminant(s) from the spent gas mixture from the medical device and returning the decontaminated spent gas to lower pressure section;

replenishing components in the medical gas mixture by addition of feed gases to maintain the recirculating medical gas composition constant; and

varying the volume of the main gas circuit to maintain the gas flow therein.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).

Figure 1 is a diagrammatical representation of an apparatus according to one embodiment of the present invention for providing a xenon/oxygen mixture to a cardiopulmonary bypass oxygenator.

Figure 2 is a diagrammatical representation of a ventilator circuit for introduction into the apparatus of Figure 1 to replace the cardiopulmonary bypass oxygenator.

Figure 3 is a diagrammatical representation of another ventilator circuit for introduction into the apparatus of Figure 1 to replace the cardiopulmonary bypass oxygenator.

Figure 4 is a diagrammatical representation of an apparatus according to another embodiment of the present invention for selectively providing a xenon/oxygen mixture to a cardiopulmonary bypass oxygenator and an artificial ventilator.

DETAILED DESCRIPTION OF THE INVENTION.

In a first aspect, the present invention is an apparatus for providing and circulating to a medical device a medical gas mixture comprising at least two components, said apparatus comprising:-

a main gas circuit for recirculating the medical gas mixture and comprising:-

a constant speed circulation pump for pumping gas through the main circuit and increasing the gas pressure from a lower pressure to a higher pressure,

a pressure maintaining valve downstream of the pump and dividing the main circuit into a higher pressure section and a lower pressure section in order to maintain a constant pressure in the higher pressure section,

a medical gas outlet in the higher pressure section,

a spent gas inlet in the lower pressure section,

a first feed gas supply inlet,

a second feed gas supply inlet downstream of the gas outlet and upstream of the pressure reduction valve,

concentration determining means for measuring the concentration of at least one component of the recirculating medical gas mixture and generating a signal indicative of said concentration,

circuit volume regulating means for varying the volume of the main circuit at a location in the lower pressure section for maintaining a predetermined gas flow to the pump and generating a signal indicative of said volume, and

means for venting gas from the main circuit;

a first feed gas supply conduit for supply to the first feed gas inlet of a first feed gas of predetermined composition;

first feed gas supply flow control means for controlling the flow of first feed gas through the first gas supply conduit in response to the signal from the concentration determining means to maintain constant the medical gas composition at the pump inlet;

a second feed gas supply conduit for supply to the second feed gas inlet of a second feed gas of predetermined composition different from the first feed gas;

second feed gas supply flow control means for controlling the flow of second feed gas through the second gas supply conduit in response to the signal from the circuit volume regulating means to maintain constant the recirculating medical gas composition; and

a medical device supply circuit for connecting the medical device to the main circuit to

receive a portion of the medical gas from the medical gas outlet thereof and to return spent gas to the spent gas inlet thereof and comprising:

flow control means for controlling flow of the medical gas to the medical device and purification means for removing contaminant(s) from the spent gas.

In a second aspect, the present invention is a medical device system comprising a medical device connected to the medical device supply circuit of the apparatus of the first aspect.

Preferably, the pressure maintaining valve is a spill valve; i.e. a valve which opens wider in response to increased pressure to pass more gas into the lower pressure section and thereby maintain the pressure in the higher pressure section. However, the valve could be a conventional pressure reduction valve.

Preferably, the circuit volume regulating means comprises expansion bellows and the means for generating a signal indicative of the volume thereof suitable is an infra-red level or, preferably, ultrasonic sensor for detecting the level of the expansion bellows in an expandable direction thereof.

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between the desired concentration and the detected concentration of oxygen may correspond to a flow through the oxygen (first) supply conduit of 1 litre per minute (l/min). Conversely, for controlling the concentration of xenon, which is relatively slowly consumed by a patient connected to the medical device, a low gain response may be more appropriate.

It is preferred that the concentration of xenon in a recirculating binary mixture with oxygen is determined with an ultrasonic gas analyser. Preferably, the ultrasonic gas analyser has an ultrahigh frequency ultrasonic transmitter, for example greater than 100 kHz. A suitable ultrasonic gas analyser is that described in ~~our co-pending UK Patent Application No. 0210021.2 filed 1st May 2002 and the corresponding~~ PCT Patent Application PCT/GB03/01877 filed 1st May 2003 ~~of even date with the present application (file reference: P8942WO)~~ (see US2006/0021421).

The ultrasonic gas analyser may be used in combination with monitoring the recirculating volume to provide other information such as the concentration of contaminants in the circuit.

Similarly, comparison of the measured concentration of oxygen and xenon, in the recirculating gas, may provide information on the concentration of contaminants such as nitrogen or carbon dioxide.

When xenon or other high value gases are used, it is preferable to direct spent or recirculating gas that may from time to time be vented into a gas recovery space. Where the high value gas is provided from a supply in a fresh gas space in a container having an ullage space, the ullage space may provide the gas recovery space. Such a container can be as described ~~in our co-pending UK Patent Application No. 0210022.0 filed 1st May 2002 and the corresponding~~ PCT Patent Application PCT/GB03/01883 filed 1st May 2003 ~~of even date with the present application (file reference: P8943WO)~~ (see US2006/0144225).

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One or more of a carbon dioxide absorber, a carbon dioxide analyser and a pressure relief device can be provided downstream from the medical device when carbon dioxide is a waste product from that device.

~~The following is a description by way of example only and with reference to the accompanying drawings of presently preferred embodiments of the invention. In the drawings:~~

~~Figure 1 is a diagramatical representation of an apparatus according to one embodiment of the present invention for providing a xenon/oxygen mixture to a cardiopulmonary bypass oxygenator;~~

~~Figure 2 is a diagramatical representation of a ventilator circuit for introduction into the apparatus of Figure 1 to replace the cardiopulmonary bypass oxygenator;~~

~~Figure 3 is a diagramatical representation of another ventilator circuit for introduction into the apparatus of Figure 1 to replace the cardiopulmonary bypass oxygenator; and~~

~~Figure 4 is a diagramatical representation of an apparatus according to another embodiment of the present invention for selectively providing a xenon/oxygen mixture to a cardiopulmonary bypass oxygenator and an artificial ventilator.~~

With reference to Figure 1, xenon/oxygen mixture in a ratio of 80% xenon to 20% oxygen is fed at inlet 13 into the main circuit 102 (a + b) of the apparatus (generally designated 101) from a

xenon/oxygen supply in fresh gas space 119 of container 121 via xenon mass flow controller (MFC) 123.

The oxygen content of main circuit 102 is topped up at inlet 12 from oxygen cylinder 125 via regulator 127 and oxygen mass flow controller (MFC) 129.

One or more (preferably four) diaphragm pumps 117 pump the xenon/oxygen mixture around the circuit 102 at a rate of up to 20 litres per minute (l/min) at a pressure of up to 150 millibar gauge (115 kPa).

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The gaseous composition is fed from outlet 10 to cardiopulmonary bypass (CPB) oxygenator 103 via medical device supply conduit 105, which is regulated by flow control valve 139, which may be set at a desired level by the operator.

CPB oxygenator 103, which is typically a membrane oxygenator, is fed unoxygenated blood from a patient 107 via unoxygenated blood conduit 109 and returned to the patient 107 via oxygenated blood conduit 111. Spent gas from the CPB oxygenator 103 is fed through spent gas return conduit 113 and then through water trap 147 and primary carbon dioxide absorber 135 to return to the main circuit section 102b upstream of pump(s) 117.

Gas passing through the spent gas return conduit 113 and medical device supply conduit 105 pass through respective bacterial filters 115 to protect the patient 107 from contamination from the apparatus 101 and vice versa.

In order to ensure that a constant flow of gas at the set pressure is supplied to the oxygenator 103 and thus available to the patient's blood, gas circulates through the main circuit 102 via pressure maintaining valve 141 downstream from the outlet to medical device supply conduit 105. Pressure maintaining valve 141 is a valve which allows gas flow only when the pressure exceeds a predetermined level, for example 30 mbarg (103 kPa) and accordingly maintains a constant pressure between the pumps 117 and the valve 141.

Downstream from the pressure maintaining valve 141, the gaseous composition is analysed for xenon content using ultrasonic xenon analyser 143 of the kind described in our co-pending UK Patent Application No. 0210021.2 filed 1st May 2002 and the corresponding PCT Patent Application PCT/GB03/01877 filed 1st May 2003 ~~of even date with the present application (file reference: P8942WO)~~ (see US2006/0021421). In an alternative arrangement (not shown) the xenon analyser is located upstream of the pressure maintaining valve 141.

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The gas is then fed via bellows 145, which expand to take up any additional volume of gas in the apparatus or contract to compensate for loss of volume in the apparatus, and receives the spent gas upstream of pump(s) 117.

The oxygen concentration in the main circuit 102 is monitored by an oxygen fuel cell sensor 131 that is shown situated in the main circuit section 102a downstream from pump(s) 117 but could be located downstream of the pressure maintenance valve 141. The gas is then fed through backup carbon dioxide absorber 133, which removes residual carbon dioxide from the recirculating gas. The carbon dioxide removed by absorbers 133 and 135 has entered via the oxygenator 103 after being flushed from the patient's blood. At least absorber 135 should be replaced with each use of the system.

Downstream from the backup carbon dioxide absorber 133, a small sample of gas is drawn from the main circuit 102 and fed to analyser unit 137 to be analysed for carbon dioxide, via an infra red gas analyser, to ensure that the carbon dioxide absorbers are working efficiently and for oxygen, via a paramagnetic gas analyser, as a backup to the oxygen fuel cell sensor 131. The sample is returned to the main circuit section 102b upstream from the pump(s) 117.

Recovery gas conduit 149 selectively feeds at least a portion of gas from the main circuit 102 at a point downstream from the backup carbon dioxide absorber 133 to the ullage space 151 of container 121, via recovery valve 153 and compressor 155. This container 121 is of the kind described in our co-pending UK Patent Application No. 0210022.0 filed 1st May 2002 and the corresponding PCT Patent Application PCT/GB03/01883 filed 1st May 2003 ~~of even date with the present application (file reference: P8943WO)~~ (see US2006/0144225).

An atmospheric vent 157 from bellows 145 enables the gas within the apparatus to be vented to atmosphere if desired.

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conventional cylinder 419 instead of the ullage-space container 121 of Figure 1 and no provision is made for recovery of xenon. Further, the oxygen fuel cell sensor 431 is provided downstream, instead of upstream, of the pressure maintaining valve 441. A water adsorber 471 is provided immediately downstream of the primary carbon dioxide absorber 435 and a carbon dioxide analyzer 472 is provided to monitor the carbon dioxide content of the spent oxygenator gas.

A ventilator supply conduit 460 regulated by flow control valve 461 connects the main circuit section 402a downstream of the pumps 417 to an essentially conventional artificial ventilator assembly via a bacterial filter ~~463~~413. The artificial ventilator assembly comprises the ventilator 463, bellows 464, oxygen fuel cell sensor 465, carbon dioxide absorber 466, carbon dioxide analyzer 467 and endotracheal tube 468 and operates generally as described with reference to Figures 2 and 3. The spent gas from the artificial ventilator assembly is returned to the main circuit via ventilator spent gas return conduit 469, including a bacterial filter 470, connected to the primary carbon dioxide adsorber ~~135~~435.

Although illustrated and described herein with reference to certain specific embodiments, the present invention is nevertheless not intended to be limited to the details shown. Rather, various modifications may be made in the details within the spirit and scope of the following claims.